OCT - 5 2011

K112007

16 510(k) SUMMARY

16.1 General Information

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765 USA Phone: 909-839-8597 Fax: 909-839-8804
Date:	July 8, 2011
Contact Person:	Wayne R. Hohman Project Manager Regulatory Affairs
Trade/Proprietary Device Name:	CARTO® 3 V2.2 EP Navigation System and Accessories
Manufacturing Part Numbers:	FG-5400-00 (with standard location pad) FG-5600-00 (with RMT location pad)
Common Device Name:	Cardiac mapping system
Classification Name:	Programmable diagnostic computer
Device Classification:	Class II, 21 CFR 870.1425 Product Code DQK
Predicate Device:	CARTO® 3 V2.0 EP Navigation System and Accessories 510(k) K103746, January 21, 2011
Manufacturing Facility:	Biosense Webster (Israel) Ltd. 4 Hatnufa Street, POB 275 Yokneam 20692 Israel

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16.2 Description of Device

The CARTO® 3 V2.2 EP Navigation System is a catheter-based atrial and ventricular mapping system designed to acquire and analyze data points, and use this information to display 3D anatomical and electroanatomical maps of the human heart in real-time. The location information needed to create the cardiac maps and the local electrograms are acquired using a specialized mapping catheters and reference devices. The system allows real-time display of electrograms and cardiac maps based on the received intra cardiac signals in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed on the display screen. The CARTO® 3 V2.2 System uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

16.3 New Features

The new features in this Special 510(k) Notification were software additions of Fluoro Effect Reduction (FER), support of Biosense Webster PENTARAY® Catheter, and support of SOUNDSTAR® *eco* Catheters with Split Handle, and hardware modification of an ECG board and addition of an Extension Cable. In addition, all modifications cleared via documentation since the prior predicate version were described.

16.4 Indications for Use

The Indications for Use for the modified device are identical to the predicate device:

The CARTO® 3 V2.2 System is intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, cardiac chamber geometry maps and ECG fragmentation maps. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be displayed in real time on the system's display screen. The CARTO® 3 V2.2 System is also intended to support EP procedures maintaining CARTO® System capabilities in the presence of a high metallic environment and magnetic field strengths up to 0.1 T and provide a data communication channel to the Stereotaxis Niobe® Catheter Navigation System. The CARTO® 3 V2.2 System includes CARTOMERGE® Plus functionality to import, register and merge CT or MRI structural images with CARTO® map's physiological information and real time catheter navigation. The system includes the Fast Anatomical Mapping (FAM) functionality that allows for the quick creation of cardiac anatomical volumes using catheters with magnetic location sensors. The system's CARTOSOUND® image integration functionality enables integration of

intracardiac echo (ICE) to enable visualization of 3D combined maps. In addition to the use of specialized navigation catheters with magnetic location sensors, the system is also intended for use with conventional, non-navigational, electrophysiology catheters without magnetic location sensors.

16.5 Summary of Non-Clinical Performance Testing

The CARTO® 3 V2.2 EP Navigation System underwent extensive bench and animal testing to verify the new and enhanced features and to demonstrate with regression testing that the new features did not negatively affect existing features. The CARTO® 3 V2.2 EP Navigation System passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

16.6 Substantial Equivalence

The Carto® 3 EP Navigation System, Version 2.2, is substantially equivalent to the legally marketed Carto® 3 EP Navigation System, Version 2.0, 510(k) K103746, cleared on January 21, 2011.

16.7 Conclusions

The bench and animal pre-clinical testing demonstrated that the CARTO® 3 V2.2 EP Navigation System is safe, effective, and performs as well as or better than the predicate device. This testing program supports the determination of substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Biosense Webster, Inc.
c/o Mr. Wayne R. Hohmann
Project Manager Regulatory Affairs
3333 Diamond Canyon Road.
Diamond Bar, CA 91765

OCT - 5 2011

Re: [510(k)] K112007
Trade/Device Name: CARTO 3 V2.2 EP Navigation System (Version 2.2)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 8, 2011
Received: September 9, 2011

Dear Mr. Hohmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 INDICATIONS FOR USE

510(k) No (if known): K112007

Device Name: CARTO® 3 V2.2 EP Navigation System

Indications for Use:

The CARTO® 3 V2.2 System is intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, cardiac chamber geometry maps and ECG fragmentation maps. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be displayed in real time on the system's display screen. The CARTO® 3 V2.2 System is also intended to support EP procedures, maintaining CARTO® System capabilities in the presence of a high metallic environment and magnetic field strengths up to 0.1 T and provide a data communication channel to the Stereotaxis Niobe® Catheter Navigation System. The CARTO® 3 V2.2 System includes CARTOMERGE® PLUS functionality to import, register and merge CT or MRI structural images with CARTO® map's physiological information and real time catheter navigation. The system includes the Fast Anatomical Mapping (FAM) functionality that allows for the quick creation of cardiac anatomical volumes using catheters with magnetic location sensors. The system's CARTOSOUND® image integration functionality enables integration of intracardiac echo (ICE) to enable visualization of 3D combined maps. In addition to the use of specialized navigation catheters with magnetic location sensors, the system is also intended for use with conventional, non-navigational, electrophysiology catheters without magnetic location sensors.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112007

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